ORIGINAL

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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-12- 18654	**88120000197**	5/15/12

COMMENTS:

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UNITED INITIATORS
driving your success

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7 May 2012

US EPA Office of Pollution Prevention and Toxics
EPA East Building - Room 6428 - Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Return Receipt Requested

SUBJECT: TSCA 8(e) Notice

Dear TSCA Section 8(e) Coordinator:

On behalf of the study sponsor named below I am submitting results for a Growth Inhibition Test on Algae with tert-Butylperoxypivalate (CAS# 927-07-1). The study sponsor is United Initiators GmbH & Co. KG.

Study details:

Reference: report study 552.440.3151 Performed by: TOXI-COOP ZRT, Hungary

Study Conclusion: See attached pages (cover sheet and pages 10 to 11of 31) from the study report.
Note: The material is referred to as "TBPPI" in the report.

This submission is not considered to be confidential. The item of concern is on the public list.

Please contact me at (440)326-2419 if you have any questions regarding this letter.

Sincerely,

Mark J. King

Mark J. King

Technical Director

CONTAINS NO CBI

TOXI-COOP ZRT
„Member of ATRC"

TOXI-COOP ZRT

Address: *8230 Balatonfüred, Arácsi út 97.*
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Growth Inhibition Test of TBPPI-75-AL on Algae (*Pseudokirchneriella subcapitata*)

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

OECD Guideline for Testing of Chemicals, Section 2, No 201, 2006.
Commission Regulation (EC) No 761/2009, Annex Part C, C.3, July 23, 2009
OPPTS 850.5400 of the United States Environment Protection Agency (EPA), 1996.

Study Director: István Ágh

Date of Draft Report: 18 April 2012

Final Report

Page 1 of 31 (including Appendix total pages 84)

Study Number: 552.440.3151

Sponsor:

United Initiators GmbH & Co KG
Dr.-Gustav-Adolph-Str. 3
D-82049 Pullach
Germany

ORIGINAL 1 FROM 2

Summary

Title	Growth Inhibition Test of TBPPI-75-AL on Algae (Pseudokirchneriella subcapitata)
Purpose	The purpose of this study was to determine the effect of the test item TBPPI-75-AL on the growth of an unicellular green algal species *Pseudokirchneriella subcapitata* (formerly: *Selenastrum capricornutum).* Exponentially growing cultures of *Pseudokirchneriella subcapitata* were exposed to various concentrations of the test item over several generations under defined conditions. The algal growth in relation to a control culture was determined over a fixed test period of 72 hours and thus, over several algal generations. The test method of application and the test species *Pseudokirchneriella subcapitata* are recommended by the test guidelines.
Test Concentrations	Test concentrations were prepared by appropriate diluting of a stock solution. Based upon the results from the preliminary experiment, nominal concentrations of 0.8; 1.8; 4.1; 9.5; 21.7 and 50.0 mg/L were investigated in the main study. Because significant toxic effect was observed in the lowest tested concentration, influence of the test item was further investigated in a complementary experiment at the following nominal concentrations: 0.07, 0.15, 0.35 and 0.80 mg/L. The measured concentrations deviated more than 20 % from the nominal during the experiments therefore the geometric mean of the measured concentrations were calculated in order to determine exposure concentrations. The corresponding calculated geometric mean concentrations were the followings: Experiment I: 0.414, 0.779, 2.383, 5.471, 12.301 and 26.531 mg/L Experiment II: 0.053, 0.096, 0.189 and 0.462 mg/L
Results	
Analytical results	The quantification of the test item was performed by a previously validated analytical method. Samples were taken from each testing concentration and the control at the start of the tests and 24 hours interval thereafter during the experiments and analysed by a reverse phase HPLC method with UV detection on a HyperPrep HS C18 column. The measured concentrations of TBPPI-75-AL varied between 36 and 106 % of the nominal concentration during the experiments.

Biological results

For the determination of the LOEC and NOEC, the calculated mean growth rates and yield at the test concentrations were tested on significant differences to the control values by Bonferroni t-Test using TOXSTAT software. The test item had a statistically significant inhibitory effect on the growth based on the average specific growth rate and yield of *Pseudokirchneriella subcapitata* after the exposure period of 72 hours in the concentration range of 0.189 – 26.531 mg/L (Bonferroni t-Test, α=0.05).

Accordingly the 72-hour overall NOEC was determined as 0.096 mg/L.

The E_rC_x and E_yC_x values of the test item and their confidence limits were calculated using Probit analysis by SPSS PC+ software.

The 72-h E_rC_{10} was determined as 0.293 mg/L and the 72-h E_rC_{50} was determined as 1.417 mg/L.

The 72-h E_yC_{10} was determined as 0.119 mg/L and the 72-h E_yC_{50} was determined as 0.422 mg/L.

All biological results are related to the geometric mean of the measured test item concentrations during the experiment.

Table 1: Influence of TBPPI-75-AL on the growth of *Pseudokirchneriella subcapitata*

Parameter (0-72 h)	**Growth rate (r)** [mg/L]	**Yield (y)** [mg/L]
EC_{10}	**0.293**	**0.119**
95 % conf. limits	0.238 – 0.351	0.097 – 0.141
EC_{50}	**1.417**	**0.422**
95 % conf. limits	1.235 – 1.635	0.377 – 0.474
NOEC	**0.096**	**0.096**
LOEC	**0.189**	**0.189**

Conclusion

In this 72-h algal growth inhibition test with *Pseudokirchneriella subcapitata*, the 72-h EC_{50} value based on growth rate was determined as 1.417 mg/L and based on yield was determined as 0.422 mg/L.

The 72-h EC_{10} value based on growth rate was determined as 0.293 mg/L and based on yield was determined as 0.119 mg/L.

The overall NOEC was determined to be 0.096 mg/L.

The results are based on the measured geometric mean concentrations.

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7 May 2012

US EPA Office of Pollution Prevention and Toxics
EPA East Building - Room 6428 - Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Return Receipt Requested

SUBJECT: TSCA 8(e) Notice

Dear TSCA Section 8(e) Coordinator:

On behalf of the study sponsor named below I am submitting results for an Acute Toxicity to Daphnia magna in a 48-hour Immobilisation Test with tert-Butylperoxypivalate (CAS# 927-07-1). The study sponsor is United Initiators GmbH & Co. KG.

Study details:

Reference: report study 552.441.3152R Performed by: TOXI-COOP ZRT, Hungary

Study Conclusion: See attached pages (cover sheet and pages 8 to 9 of 23) from the study report.
Note: The material is referred to as "TBPPI" in the report.

This submission is not considered to be confidential. The item of concern is on the public list.

Please contact me at (440)326-2419 if you have any questions regarding this letter.

Sincerely,

Mark J. King

Mark J. King

Technical Director

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TC

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Acute Toxicity of TBPPI-75-AL to *Daphnia magna* in a 48-hour Immobilisation Test

This study followed the procedures indicated by the following internationally accepted guidelines and recommendations:

Commission Regulation (EC) No 440/2008, Annex Part C, C 2, May 30, 2008
OECD Guideline No. 202, updated 13th April 2004 and
OPPTS 850.1010 of the United States Environment Protection Agency (EPA), 1996.

Study Director: István Ágh

Date of Final Report: 20 March 2012

Final Report

Study Number: 552.441.3152R

Sponsor:

United Initiators GmbH & Co KG
Dr.-Gustav-Adolph-Str. 3
D-82049 Pullach
Germany

ORIGINAL 1 FROM 2

Summary

Title

Acute Toxicity of TBPPI-75-AL to *Daphnia magna* in a 48-hour Immobilisation Test

Purpose

The purpose of this study was to evaluate the influence of the test item TBPPI-75-AL on the mobility respectively survival of Daphnia magna. Young Daphnia were exposed in an immobilisation test to aqueous test media containing the test item for 48 hours at a range of concentration. Because the concentration of the test item was expected to decrease more than 20 % from the nominal during the exposure period, the test was performed under semi-static conditions. The frequency of the water renewal periods was 24 hours.

Test concentrations

Based upon the results from the preliminary experiments, nominal concentrations of 4.3; 9.4; 20.7; 45.5 and 100.0 mg/L were investigated in the main study.

The measured concentrations deviated more than 20 % from the nominal during the experiments therefore the geometric mean of the measured concentrations were calculated in order to determine exposure concentrations.

The corresponding calculated geometric mean concentrations were the followings: 2.94, 6.51, 14.44, 31.76 and 64.65 mg/L.

Results

Analytical results

The quantification of the test item was performed by a previously validated analytical method. Samples were taken from each testing concentration and the control at the start and at the end of each renewal period and analysed by a reverse phase HPLC method with UV detection on a HyperPrep HS C18 column.

The measured concentrations of TBPPI-75-AL varied between 70 and 86 % of the nominal concentration during the experiments.

Biological results

The following table provides a summary of the influence of TBPPI-75-AL on immobility of Daphnids.

The 24-h and 48-h EC_{50} values of the test item and their confidence limits were calculated using Probit analysis by SPSS PC+ software.

For determination of NOEC, LOEC and EC_{100} were determined directly from the raw data.

All biological results are related to the measured geometric mean test item concentrations.

Table 1: Effect of TBPPI-75-AL on the mobility of daphnids

Parameter [mg/L]	Time period	
	24 h	**48 h**
EC_{50}	**25.48**	**6.99**
95 % conf. limits	20.36 – 31.79	5.87 – 8.51
48 h-NOEC	**2.94**	
48 h-LOEC	**6.51**	
48 h- EC_{100}	**14.44**	

Conclusion

In this 48-hour acute toxicity test with *Daphnia magna* the 48 h EC_{50} value was determined as 6.99 mg/L, and the 48 h NOEC was determined to be 2.94 mg/L. The results are based on the measured geometric mean test item concentrations.

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